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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MALAMUD, DEBORAH LESLIE

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/648,844	Applicant(s) KRISHNAN, SUBRAMANIAM C.	
	Examiner Deborah Malamud	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 11, 17, 18 and 22-37 is/are pending in the application.
- 4a) Of the above claim(s) 22-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 17, 18, 21, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. The examiner acknowledges the amendments received 16 March 2007. Claims 1-10, 12-16 and 19-20 are cancelled; new claims 21-37 are added; claims 11, 17-18 and 21-37 are pending.

### *Election/Restrictions*

2. Newly submitted claims 22-35 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the inventions as specified by claims 11 and claims 22-35 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as required by claim 11 can be used to identify the fossa ovalis in a way not claimed by the methods of claims 22-35, such as through fluoroscopy.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22-35 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Claim Rejections - 35 USC § 112***

4. In view of the amendments to the claims, the examiner withdraws the rejection of claim 11 under 35 U.S.C. 112, second paragraph.

***Drawings***

5. The drawings were received on 16 March 2007. These drawings are accepted by the examiner.

***Claim Objections***

6. Claim 37 is objected to because of the following informalities: claim 37 appears to depend on itself. For purposes of examination, the examiner will consider this claim to depend on 36. Appropriate correction is required.

***Response to Arguments***

7. Applicant's arguments, see pages 9-10 of "Remarks," filed 16 March 2007, with respect to Cohen and Swanson and the amended subject matter, have been fully considered and are persuasive. The rejection of claims 11 and 17-18 under these references has been withdrawn.
8. Applicant's arguments filed 16 March 2007 have been fully considered but they are not persuasive. The applicant argues, "Svenson et al in fact requires bipolar sensing electrodes and a unipolar electrode but does not denote that the electrodes individually are capable of providing both unipolar and bipolar measurements. Therefore, Svenson

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et al fail to teach the catheter as recited in independent claim 11." It is to be noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Svenson's mapping catheter, as described in column 5, lines 35-45) "is advanced through the hand-held probe until it comes in contact with the inside of the heart. The multiple tips of the mapping catheter are then used as a bipolar system to map the electrical potential in the area of contact. Alternatively, another catheter can be inserted into the mapping catheter and its tip can be used in conjunction with the mapping catheter to perform the bipolar sensing of electrical potentials." Svenson's catheter is therefore capable of bipolar and unipolar sensing, as required by the claim. Furthermore, nothing prevents Svenson's mapping catheter from concurrent bipolar and unipolar sensing. The rejection of claim 11 under Svenson is therefore maintained.

***Claim Rejections - 35 USC § 102***

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Svenson et al (U.S. 5,409,008). For a complete discussion of the claimed elements, please see the previous Non-Final Office Action, and above.

***Claim Rejections - 35 USC § 102/103***

11. Claims 21 and 36 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Svenson et al (U.S. 5,409,008). Svenson discloses (col. 2, lines 30-36) "a mapping catheter which includes a polymer member, bipolar sensing electrodes placed on a distal end of said polymer member, a spaced unipolar electrode at a spaced distance from said bipolar electrodes, and a lumen within said polymer member for the passage of a laser catheter or other instrument." Svenson further discloses, (col. 3, lines 13-17) "a laser delivery catheter can be passed through the center hollow lumen of the mapping catheter and the myocardium irradiated for a predetermined period of time to ablate the site." The examiner considers this to be a hollow lumen, a first electrode positioned on a distal end of the catheter, and a second electrode spaced proximally from the first electrode and positioned on the catheter. Svenson further discloses (col. 3, lines 53-64; Figure 1) "mapping catheter (10) including the catheter tip (12), the stainless steel support tube (14), the hand piece (16), and the Y-connector (18). The hand piece joins the Y-connector and the stainless steel support tube together and includes the electrical junction (20) of the wires (21a-21c) with electrical connectors (22a-22c), which in this example are insulated alligator clips. A polymer tube-like sheath (24) connects between the catheter tip (12) and the hand piece, and houses a plurality of wires (21a-21c) between the polymer sheath and the underlying stainless steel support tube." The examiner considers this to be a hollow sheath having a distal end. It is to be noted that the functional language and introductory statement of intended use of claims 21 and 36,

have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Svenson utilizes a mapping catheter as claimed by the applicant, Svenson is therefore capable of being inserted into a sheath (such as polymer sheath 24), having a needle urged through, and being used as a dilator for performing a transseptal puncture and locating the fossa ovalis, on the basis of the claimed parameters. In addition nothing prevents the catheter of Svenson from being performing these functions. Therefore, they are capable of locating and penetrating the fossa ovalis and being used with a sheath and a needle.

12. Svenson further discloses, (col. 2, lines 56-62) "The current catheter provides a tool for more accurately mapping the electric potential of very small areas of the inner chambers of the heart. In addition, the catheter provides a way to simultaneously obtain the QRS and EKG signals, thus providing a method to more rapidly and accurately identify the focus or foci of the tachycardia." The examiner considers this system therefore inherently to include a recording device for recording electrograms, the recording device in electrical communication with the electrodes of the catheter. In the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a recording device for recording electrograms in order to display the data gathered by the electrodes for future diagnosis.

***Claim Rejections - 35 USC § 103***

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.



14. Claims 17-18 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svenson et al (U.S. 5,409,008). For a complete discussion of the claimed elements, please see the previous Non-Final Office Action. Regarding new claim 37, Svenson discloses the claimed invention but does not disclose expressly the tapered distal end of the catheter. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the distal end of the catheter as taught by Svenson, with a tapered distal end, because the applicant has not disclosed the tapered end provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the uniform distal end as taught by Svenson, because Svenson's mapping catheter is able to be inserted in the heart in order to obtain cardiac electrical signals. Therefore, it would have been an obvious matter of design choice to modify Svenson's catheter to obtain the invention as specified in the claims. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a second electrode spaced from the first electrode by a distance of between about 2 and about 4 mm, since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

### **Conclusion**

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

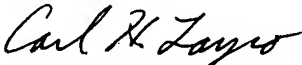
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
CARL LAYNO  
PRIMARY EXAMINER

  
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Patent Examiner  
Art Unit 3766